Intima media thickness in control subjects who represent the general population in the Netherlands - The SILHOUET study

Published: 15-08-2007
Last updated: 08-05-2024

To organize one pool of control subjects for IMT studies.

Ethical review	Approved WMO
Status	Pending
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational invasive

Summary

ID

NL-OMON31327

Source
ToetsingOnline

Brief title
SILHOUET

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
carotid artery, Intima media thickness

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Achilles tendon thickness, control group, Intima media thinkness

Outcome measures

Primary outcome

Several parameters will be measured among which the most important ones are:

IMT, Achilles tendon (AT) thickness, lipid profile and other standard

biochemistry and haematology parameters. Subjects will also undergo a general

physical exam. Blood samples will be stored for future parameters related to

cardiovascular disease which are specific for future studies.

Secondary outcome

Not applicable.

Study description

Background summary

The intima media thickness (IMT) is considered a validated surrogate end point for the status of atherosclerosis as well as present and future vascular risk. It is increasingly measured in human studies as a surrogate end point for cardiovascular risk. In many trials, the mean IMT of certain patient groups is compared to that of a control group in order to assess the risk. This protocol describes a study in which one control population will be assembled to avoid overlap in work for several studies.

Study objective

To organize one pool of control subjects for IMT studies.

Study design

A cross-sectional study, and the subjects will visit the hospital only once for this study.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Subjects will have to visit the hospital only once, during which IMT and AT thickness will be measured by means of ultrasonography, a simple and non-invasive imaging technique. Furthermore, one blood sample of 80 mL will be taken, and subjects will undergo a physical exam. We consider the risks negligible and the burden minimal.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- male and females, aged 18-75 y

- subjects must be willing and able to give written informed consent

Exclusion criteria

- Any lipid disorder, including familial hypercholesterolemia (FH), familial defective apolipoprotein B (FDB), familial combined hypercholesterolemia (FCH) or another primary dyslipidemia;
- Subjects of whom an IMT cannot be properly measured, due to e.g. neck/throat surgery;
- BMI > 35 kg/m2;
- Subjects who drink alcohol excessively defined as more than 21 units/wk;
- Any clinical significant medical condition that could interfere with being a control participant.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2007
Enrollment:	500
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL18195.018.07